#### JAN 0 7 2002

### 3.2 Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 C.F.R. §807.92.

The submitter of this premarket notification is:

Steve Singlar Regulatory Engineer Philips Medical Systems Philips Ultrasound Division 3000 Minuteman Road, MS 0135 Andover, MA 01810

Tel: (978) 659-2101 Fax: (978) 975-7324

This summary was prepared on November 19, 2001.

The proprietary name of the device is the M2540 Diagnostic Ultrasound System. In combination with the new transducers - 21373B, 21422A, 21425A, 21426A, 21475A - are commonly known as a diagnostic ultrasound system and transducers.

These devices are classified as follows:

90IYN	Ultrasonic Pulsed Doppler Imaging System
90IYO	Ultrasonic Pulsed Echo Imaging System
90ITX	Diagnostic Ultrasound Transducer

As stated in 21 CFR, parts 892.1550, 892.1560 and 892.1570, each of these generic types of devices have been classified as Class II.

The M2540 is a diagnostic ultrasound device. It consists of a system console containing the power supply and electronic circuitry required to generate the image, a display screen, and a connection to the separate transducers. It is substantially equivalent to the ultrasound systems including the M2410 Ultrasound system with transducers.

The 21422A, 21425A, 21446A, 21475A transducers are substantially equivalent to the Philips sector, linear and endo-cavity ultrasound transducers.

The M2540 system and transducers function in a manner identical to all ultrasound systems and transducers. The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo-electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The differing acoustic properties of the tissues in the body reflect some of the transmitted energy back to the transducer, where it is converted back to electrical signals and sent back to the system. In the system, advanced signal processing technologies convert the returned signals into images of the tissues. The Doppler functions of this system process the Doppler shift frequencies from the echoes of moving targets (such as blood), to detect and graphically display the Doppler shifts of these tissues as flow.

The M2540 is intended for diagnostic ultrasound imaging and fluid flow analysis.

The M2540 is substantially equivalent in safety and effectiveness to the predicates identified above:

- Both the predicate device and the M2540 are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- Both the predicate device and the M2540 have the same gray-scale and Doppler capabilities.
- Both the predicate device and the M2540 use essentially the same technologies for imaging, Doppler functions and signal processing.
- Both the predicate device and the M2540 have acoustic output levels below the Track 3 FDA limits.
- Both the predicate device and the M2540 are manufactured under equivalent quality systems.
- Both the predicate device and the M2540 are manufactured of materials with equivalent biosafety. The materials have been evaluated and found to be safe for this application.
- Both the predicate device and M2540 are designed and manufactured to the same electrical and physical safety standards.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

### JAN 0 7 2002

Phillips Medical Systems % Mr. Mark Job 510(k) Program Manager TÜV Product Service 1775 Old Highway 8 NW, Suite 104 NEW BRIGHTON MN 55112-1891

Re: K014191

Trade Name: M2540 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasound pulsed doppler imaging system

Regulatory Class: II Product Code: 90 IYN

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulatory Class: II Product Code: 90 IYO

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II Product Code: 90 ITX Dated: December 20, 2001 Received: December 21, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the M2540 Diagnostic Ultrasound System, as described in your premarket notification:

#### Transducer Model Number

21221B (C1914C) Non-Imaging Pencil Transducer 21223B (D5014V) Non-Imaging Pencil Transducer 21228B (D1914V) Non-Imaging Pencil Transducer 21321A (C3540) Curved Linear Array Transducer 21330A (S4) Sector Transducer 21336A (E6509) Endocavi ty Transducer 21350A (S8) Sector Transducer 21359A (L7535) Linear Array Transducer 21360A (L5035) Linear Array Transducer 21369A (Omni II) TEE Sector Transducer 21373A (C5040) Curved Linear Array Transducer 21373B (C5040) Curved Linear Array Transducer 21376A (L1038) Linear Array Transducer 21380A (S12) Sector Transducer 21390A (15-61) Linear Array Transducer 21422A Sector Transducer 21425A Curved Linear Array Transducer 21446A Endocavity Transducer 21475A Linear Array Transducer

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Robert A Phillips at (301) 594-1212.

Sincerely yours,

Mancy C broglon Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

#### 4.3.2 Indications for Use Tables

1014191

#### DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

510(k) number: K 0/4/9/

Device name: Philips Medical Systems M2540 Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic	N		N	N	N	N	N	
	Fetal	N	N	N	N	N	N	N	
	Abdominal	N	N	N	N	N	N :	N	
•	Intra-operative (vascular/epicardial)	N	N	N	N	N	N	N	
	Intra-operative (Neuro)	N	N	N		N	N	N	
	Laparoscopic					,			
Fetal Imaging	Pediatric '	N	N	N	N	N	N.	-nN	
& Other	Small Organ (thyroid, scrotum, breast)	N	N	N		N	Ŋ	N	
	Neonatal Cephalic	N	N	N	N	N	N	N	
	Adult Cephalic	N	N	N	N	N	N	N	
	Trans-rectal	N	N	N		N	Ŋ	N	
	Trans-vaginal	N	N	N		N	N	N	
	Trans-urethral								
	Trans-esoph. (non-Card.) Intra-luminal						•		
	Other (Gynecological)	N	N	N	N	N	N	N	
	Cardiac Adult	N	N	N	N	N	N	N	
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N	
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N	
	Other (Fetal)	N	N	N		N	N	N	
Peripheral	Peripheral vessel	N	N	N	N	N	N	N	
Vessel	Other (Specify)								
	Musculo-skel (conventional)	N	N	N	· · · · · · · · · · · · · · · · · · ·	N	N	N	
	Musculo-skel (superficial)	N	N	N		N	N	N	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

\*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

NO previous 510(k) submissions are associated with this product.

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Prescription Use (Per 21 CFR 801.109)

and Radiolog

510(k) Number

51<sup>1</sup>

510(k) Number: K\_

Clinical Applicati	Diagnostic ultrasound imag			peration	, <del>-</del>			
General	Specific	B	I M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)			. ", _	0.,2	Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic	<del>                                     </del>		<u> </u>				
Ophulannic	Fetal	<del> </del>	<del> </del>					
	Abdominal	<del> </del>		<del>                                     </del>				
		1	-		<del>                                     </del>			
	Intra-operative (Specify)	╂	<del> </del> -	<del> </del>				
	Intra-operative (Neuro)	-	<del> </del>	<del>                                     </del>				
Patel Language	Laparoscopic		<del> </del>	<del>                                     </del>				
Fetal Imaging	Pediatric	╂	<del> </del>	<del> </del>				
& Other	Small Organ (Specify)	ł	<del> </del>	<del> </del>				
	Neonatal Cephalic	<b>-</b>	<del> </del>	<b> </b>				
	Adult Cephalic	<b>-</b>		<b> </b>	ļ			
	Trans-rectal	<b></b>	<b> </b> -	<del>                                     </del>				<u> </u>
	Trans-vaginal	<del> </del>			<b></b>		·	
	Trans-urethral	<b>-</b>	ļ	ļ				<u> </u>
	Trans-esoph. (non-Card.)	ļ						<del> </del>
	Intra-luminal	<b>-</b>	<u></u>	ļ				
	Other (Specify)		<u>.</u>					
	Cardiac Adult				N		· · · · · · · · · · · · · · · · · · ·	
Cardiac	Cardiac Pediatric	<b></b>			N			
	Trans-esoph. (Cardiac)	<u> </u>		ļ				ļ.,
	Other (Specify)	1						
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
N= new indication	; P= previously cleared by FDA;	E= add	ded und	der Appe	ndix E			
*Other modes inc			*					
Combined modes:	None.							
Previous submissi	on: K002470, Adult & Pediatric	cardiac						
:								
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Prescription Use (	Per 21 CFR 801.109)  (Division	Na	me	406	i voqe	lon	-	

and Radiological Devices

510(k) Number\_

510(k) Numbe	r: <u>K</u>							
System:	10.4							
	ducer: 21223B (D5014V) Non-Imaging Pencil transducer							
Intended Use:	Diagnostic ultrasound imag	ing of	r fluid	flow a	nalysis o	f the huma	in body as fo	llows:
Clinical Applicati				eration				
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							
:	Abdominal							·
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
Fetal Imaging	Pediatric							
& Other	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
·	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Specify)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral vessel			N	N			
Vessel	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							
N= new indication	n; P= previously cleared by FDA	; E= ac	lded ur	ider Appe	ndix E			
*Other modes: No								
Combined modes								
Previous submiss	ion: K002470, Peripheral vascula	ar						
<b>.</b>								
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and Radiological Devices

510(k) Number \_\_

Division of Reproductive, Abdominal,

System:	Philips Medical Systems N					d System		•
Transducer:		1agin;	g pen	cil tran	sducer			
Intended Use:	Diagnostic ultrasound imag	ging o	r fluic	l flow a	nalysis o	f the huma	in body as fo	llows:
Clinical Applicat	tion	Mod	e of O	peration				
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)	1	<u> </u>			Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							İ
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic						1	
Fetal Imaging	Pediatric							
& Other	Small Organ (Specify)							
	Neonatal Cephalic							İ
	Adult Cephalic			N	N			
	Trans-rectal							
	Trans-vaginal						:	
	Trans-urethral							· · ·
	Trans-esoph. (non-Card.)							
	Intra-luminal				l		<u> </u>	
	Other (Specify)						•	
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
·	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral vessel	T		N				
Vessel	Other (Specify)		1					
•	Musculo-skel (conventional)		Γ					
	Musculo-skel (superficial)				1			
N= new indication	on; P= previously cleared by FDA	\; E= a	dded u	nder App	endix E			

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Previous submission: K002470 for Peripheral vascular

\*Other modes: None Combined modes: None

510(k) Number: K

(Division Sign-Off) Division of Reproductive, Abdom and Radiological Devices 510(k) Number ...

510(k) Number	er: <u>K</u>
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21321A (C3540) Curved linear array transducer

Intended Use: Diagnost	ic ultrasound imaging o	r fluid flow analysis of	the human body as follows:
242022000000000000000000000000000000000	<u> </u>		

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N	N	
	Abdominal	N	N	N		N	N	N	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal Imaging	Pediatric	N	N	N		N	N	N	
& Other	Small Organ (thyroid,	N	N.	N		N	N	N	
	scrotum, breast)	<u> </u>							
	Neonatal Cephalic	<u> </u>							
	Adult Cephalic	ļ							
	Trans-rectal		<u></u>	ļ.,					
	Trans-vaginal					<u></u>			
	Trans-urethral	<u> </u>	<u> </u>						
	Trans-esoph. (non-Card.)								
	Intra-luminal	<u> </u>							
	Other (Gynecological)	N	N	N		N	N	N	
	Cardiac Adult				•				
Cardiac	Cardiac Pediatric	<u> </u>							
	Trans-esoph. (Cardiac)								
	Other (Specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	N	
Vessel	Other (Specify)								
	Musculo-skel (conventional)								
	Musculo-skel (superficial)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: K002470 for fetal, abdominal and PV; K990400 for fetal, pediatric, abdominal, small parts and PV

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Prescription Use (Per 21 CFR 801.109) (Division Sign-Off)
Division of Reproductive, Abdominat, and Radiological Devices K0141

510(k) Number \_

510(k) Numbe	er: <u>K</u> _
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System
Transducer	21330A (S4) Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applica	Diagnostic uttrasound imag			eration				
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic	N		N	N	N	N	N
	Fetal	N	N	N	N	N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)							<u> </u>
i.	Intra-operative (Neuro)							
	Laparoscopic	<u> </u>						
Fetal Imaging	Pediatric	N	N	N	N	N	N	N
& Other	Small Organ (Specify)							
	Neonatal Cephalic	<u> </u>		<u> </u>				
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal	1						
	Trans-urethral							
<u>.</u>	Trans-esoph. (non-Card.)							
	Intra-luminal							
	Other (Gynecological)	N	N	N	N	N	N	N
	Cardiac Adult	N	N.	N	N	.N	N	N
Cardiac	Cardiac Pediatric	N	N	N	N	N	. N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N	N	N	N	N
Vessel	Other (Specify)							·
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E- added under Appendix E
*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler
Tissue Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

Previous submission: K002470 for Abdominal, Adult Cephalic, Cardiac, PV, Fetal and Ophthalmic; K990400 for Abdominal, Adult cephalic, Adult Cardiac; K990339 for Abdominal, Adult cephalic, Cardiac, Fetal and Ophthalmic; K980687 for Abdominal, Adult Cephalic, Fetal, Adult Cardiac, Ophthalmic and Harmonic Imaging

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Prescription Use (Per 21 CFR 801.109)	Manene
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(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number \_\_\_\_

System:	Philips Medical Systems M2540 Diagnostic Ultrasound System								
Transducer:	21336A (E6509) Endoca	vity tr	ansdı	ıcer					
Intended Use:	Diagnostic ultrasound ima	iging o	r fluid	l flow a	nalysis o	f the huma	ın body as fo	llows:	
Clinical Applicat	ion	Mod	e of Op	eration					
General	Specific	В	M	PWD	CWD	Color	Combined	Other*	
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)	
Ophthalmic	Ophthalmic	1							
	Fetal	N	N	N		N	N	N	
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal Imaging	Pediatric		<u></u>				•		
& Other	Small Organ (Prostate)	N	N	N		N	N	N	
	Neonatal Cephalic								
	Adult Cephalic		<u> </u>						
	Trans-rectal	N	N	N		N	N	N	
	Trans-vaginal	N	N	N		N	N	N	
	Trans-urethral		:		*				
	Trans-esoph. (non-Card.)								
•	Intra-luminal	<u> </u>			:		·		
·•	Other (Gynecological)								
	Cardiac Adult		•						
Cardiac	Cardiac Pediatric	I					:		
	Trans-esoph. (Cardiac)								
	Other (Specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E \*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color Previous submission: K990339 for Fetal, Endorectal, Endovaginal, Small Parts; K972348 Endovaginal, Endorectal, Gynecological, Obstetrics, Urological

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Prescription	Use (Per	21 CFR	801.109)
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Peripheral Vessel

Peripheral vessel

Musculo-skel (conventional) Musculo-skel (superficial)

Other (Specify)

510(k) Number: K

(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(k) Number \_\_\_\_\_

510(k) Numbe	er: <u>K</u>
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21350A (S8) Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic	1		<del>                                     </del>					
	Fetal	N	N	N		N	N	N	
	Abdominal	N	N	N	N	N	N	N	
	Intra-operative (Specify)								
	Intra-operative (Neuro)							<u> </u>	
	Laparoscopic								
Fetal Imaging	Pediatric	N	N	N	N	N	N	N	
& Other	Small Organ (Specify)								
	Neonatal Cephalic	N	N	N		N	N	N	
	Adult Cephalic								
	Trans-rectal		·						
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Intra-luminal						· · · · · · · · · · · · · · · · · · ·		
	Other (Pelvic)	N	N.	N	N	N	N	N	
	Cardiac Adult	N	N	N	N	N	N		
Cardiac	Cardiac Pediatric	N	N·	N	N	N	N	N	
	Trans-esoph. (Cardiac)								
	Other (Specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	N	
Vessel	Other (Specify)								
	Musculo-skel (conventional)								
	Musculo-skel (superficial)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

\*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

Previous submission: K002470 for abdominal, adult & pediatric cardiac

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(Division Sign-Off	) /	,	1
Division of Reproc		bdominal,	
and Radiological ( 510(k) Number	Devices	KO141	91
2 (O(K) NUMBER			

510(k) Number	er: <u>K</u>
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System
(T)	OLOGO A CHESCE Y

Transducer: 21359A (L7535) Linear array transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application			eration				
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
	Fetal							
-	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic	<u> </u>						
Fetal Imaging	Pediatric	N	N	N		N	N	N
& Other	Small Organ (thyroid,	N	N	N		N	N	N
	scrotum, breast)							
	Neonatal Cephalic	<u> </u>						
	Adult Cephalic	<b></b>						
	Trans-rectal	ļ						ļ
	Trans-vaginal	<u> </u>						
	Trans-urethral	<u> </u>						
	Trans-esoph. (non-Card.)	<u>!</u>						
	Intra-luminal	<u> </u>						
	Other (Specify)	<u> </u>		•				
	Cardiac Adult	<u>[</u>	:					
Cardiac	Cardiac Pediatric	<u> </u>						
	Trans-esoph. (Cardiac)	<u> </u>						
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N		N	N	N
Vessel	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

\*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

Previous submission: K954028 for PV, Pediatrics, Abdominal, Small Parts, and Musculo-skeletal (conventional)

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Prescription Use (Per 21 CFR 801.109)

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(Division Sign-Off)			
Division of Reprode	uctive, A	$b$ dominal, $\check{\ }$	•

510(k) Number \_\_\_\_

and Radiological Devices

510(k) Numbe	er: <u>K</u>
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System
Transducer	21360A (15035) I incar array transducar

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Applica	tion	Mod	e of O	peration				
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic	<del> </del>	1	-		Doppiei	(Specify)	(Specify)
Ophulaimic		<del></del>	-				<u>                                     </u>	
	Fetal	<b> </b>	<del> </del>	ļ			ļ	
	Abdominal	N	N	N	<u> </u>	N	N	N
	Intra-operative (Specify)		<u> </u>					
	Intra-operative (Neuro)	<b></b>	ļ					
	Laparoscopic	<u> </u>	<u> </u>	1				
Fetal Imaging	Pediatric	N	N	N		N	N	N
& Other	Small Organ (thyroid,	N	N	N		N	N	N
	scrotum, breast)							
	Neonatal Cephalic	<u></u>						
	Adult Cephalic	1						
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral						,	
	Trans-esoph. (non-Card.)							•
	Intra-luminal	I	:					
	Other (Specify)		,				3	
	Cardiac Adult							
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	1				,		
	Other (Specify)							
Peripheral	Peripheral vessel	N	N	N		N	N	N
Vessel	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)					1		

N= new indication; P= previously cleared by FDA; E= added under Appendix E	
*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging	_
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color	
Previous submission: K954028 for Vascular, Pediatrics, Musculo-Skeletal (conventional) and Abdominal.	_

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Nanc	4 C Brondon
(Division Sign-Off) Division of Reproductive, and Radiological Devices 510(k) Number	Andominal

510(k) Number: K

Cardiac

Peripheral

Vessel

210(K) 14milio	A · IX							
System:	Philips Medical Systems				Iltrasour	nd System		
Transducer:	21369A (Omni II) TEE	Sector	trans	ducer				
Intended Use:	Diagnostic ultrasound ima	aging o	r fluic	i flow a	nalysis o	f the huma	n body as fo	llows:
Clinical Applica	<del> </del>			eration				
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal Abdominal Intra-operative (Specify) Intra-operative (Neuro) Laparoscopic Pediatric Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal							
	Trans-vaginal Trans-urethral		<u> </u>	1				

N= new indication; P= previously cleared by FDA; E= added under Appendix E \*Other modes: Angio, Doppler Tissue Imaging, Directional Angio Combined modes: Duplex = 2D + Doppler Previous submission: K954028 for Adult & pediatric cardiac, transesophageal

N

N

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Trans-esoph. (non-Card.)

Intra-luminal Other (Specify)

Cardiac Adult

Cardiac Pediatric

Other (Specify) Peripheral vessel

Other (Specify)

Trans-esoph. (Cardiac)

Musculo-skel (conventional) Musculo-skel (superficial)

Prescription Use (Per 21 CFR 801.109) (Division Sign-Off) Division of Reproductive, Abdominal,

and Radiological Devices 510(k) Number \_\_

510(k) Number	er: <u>K</u>
	Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21373A (C5040) Curved Linear array transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation							
General	Specific	В	М	PWD	CWD	Color	Combined	Other*		
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)		
Ophthalmic	Ophthalmic									
	Fetal	N	N	N		N	N	N		
	Abdominal	N	N	N		N	N	N		
	Intra-operative (Specify)									
	Intra-operative (Neuro)									
	Laparoscopic									
Fetal Imaging	Pediatric	N	N	N		N	N	N		
& Other	Small Organ (Specify)									
	Neonatal Cephalic									
İ	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Intra-luminal									
	Other (Gynecological)	N	N	N		N	N	N		
	Cardiac Adult									
Cardiac	Cardiac Pediatric									
	Trans-esoph. (Cardiac)		L							
	Other (Fetal)	N	N	N		N	N	N		
Peripheral	Peripheral vessel	N	N	N		N	N	N		
Vessel	Other (Specify)									
	Musculo-skel (conventional)									
	Musculo-skel (superficial)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E	
*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging	
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color	
Previous submission: (K954028) for Fetal, Small Parts, Abdominal, Neonatal Cephalic, Cardiac and Vascular.	

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Division of Repr	oductive, A	bdominal,		
and Radiologica	Devices	K01414	<i>7  </i>	
510ki Number.		10171	<u> </u>	

510(k) Numb	er: K
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System
•	Annual Committee of the

Transducer: 21373B (C5040) Curved Linear array transducer
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation						
General Specific (Track I Only) (Tracks I & III)		В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
	Fetal	N	N	N		N	N	N_	
	Abdominal	N	N	N		N	N	N	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
Fetal Imaging	Pediatric	N	N	N	ļ	N	N N	N	
& Other	Small Organ (Specify)								
	Neonatal Cephalic							ļ	
•	Adult Cephalic			ļ					
	Trans-rectal			<u> </u>	ļ				
	Trans-vaginal			<u> </u>				<b> </b>	
•	Trans-urethral			ļ				ļ	
	Trans-esoph. (non-Card.)	<u> </u>		ļ	ļ			<u> </u>	
	Intra-luminal		<u> </u>	ļ	ļ			N	
	Other (Gynecological)	N	N	N		N	N	IN	
	Cardiac Adult	<u> </u>	<u> </u>	<u> </u>		<u> </u>		ļ	
Cardiac	Cardiac Pediatric				<u> </u>			ļ	
	Trans-esoph. (Cardiac)	<u> </u>	ļ	<b></b>	<b> </b>		N	N	
	Other (Fetal)	N	N	N		N	N	<del> </del>	
Peripheral	Peripheral vessel	N	N	N .		N N	N	N	
Vessel	Other (Specify)				<u> </u>			<del> </del>	
	Musculo-skel (conventional)			ļ	<b> </b>			<del> </del>	
	Musculo-skel (superficial)	<u>l</u> .					<u> </u>	<u> </u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging
Combined modes: Dupley = 2D + Doppler: Tripley = 2D + Doppler + Color
Previous submission: the 21373A was previously cleared (K954028) for Fetal, Small Parts, Abdominal, Neonatal
Cephalic, Cardiac and Vascular.
Cephane, Cardiae and Vascular.

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Prescription Use (Per 21 CFR 801.109)	Nancial Brosdon
	(Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices 510(c) Number K014191

510(k) Number	er: K
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System
Transducer:	21376A (L1038) Linear transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	В	М	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
Fetal Imaging	Pediatric	N	N	N		. N	N	N
& Other	Small Organ (Scrotum,	N	N	N		N	N	N
	Thyroid, Breast)	<u> </u>				ļ		
	Neonatal Cephalic		ļ			<b> </b>		
	Adult Cephalic							<b></b>
	Trans-rectal							
	Trans-vaginal				ļ			ļ
	Trans-urethral		<u> </u>					
	Trans-esoph. (non-Card.)	<u> </u>				ļ		
	Intra-luminal		<b></b>					
	Other (Specify)							
	Cardiac Adult							
Cardiac	Cardiac Pediatric		l			<u> </u>		
	Trans-esoph. (Cardiac)							
	Other (Specify)		<u> </u>					
Peripheral	Peripheral vessel	N	N	N		N	N	N
Vessel	Other (Specify)							
	Musculo-skel (conventional)	N	N	N		N	N	N
	Musculo-skel (superficial)	N	N	N		N	N	N

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging, Doppler
Tissue Imaging.
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: K990400 for Small parts, Peripheral Vascular and Musculo-skeletal (Conventional & Superficial).

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Prescription Use (Per 21 CFR 801.109)	Money & Grospan
	(Division Sign-Off) Division of Reproductive, Abdominal,
	and Radiological Devices KD14191

510(k) Nun	nber: <u>K</u>
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System
700 I	242004 (012) 0 - 4 4

Transducer: 21380A (S12) Sector transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
	Fetal Abdominal								
	Intra-operative ((vascular/epicardial) Intra-operative (Neuro)	N	N	N	N	N	N		
Fetal Imaging	Laparoscopic Pediatric	N	N	N	N	N	N	N	
& Other	Small Organ (Specify)	I	11	IN	11	11		I	
	Neonatal Cephalic Adult Cephalic	N	N	N	N	N	N	N	
•	Trans-rectal Trans-vaginal								
	Trans-urethral		1		·				
	Trans-esoph. (non-Card.) Intra-luminal Other (Specify)		•						
	Cardiac Adult	N	N	N	N ·	N	N		
Cardiac	Cardiac Pediatric Trans-esoph. (Cardiac) Other (Specify)	N	Ŋ	N	N	N	N		
Peripheral Vessel	Peripheral vessel Other (Specify) Musculo-skel (conventional)	N.	N	N	N	N	N	Ņ	
	Musculo-skel (superficial)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging, Doppler Tissue Imaging
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color
Previous submission: K971116 for Intraoperative (cardiovascular), Pediatric, Cardiac (Adult & Pediatric), Peripheral
Vascular

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
5 (C)(k) Number K014-(91)

510(k) Number	er: <u>K</u>
	Philips Medical Systems M2540 Diagnostic Ultrasound System
ors i	21200 t (15 (1) T :

Transducer: 21390A (15-61) Linear array transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic								
	Fetal Abdominal								
	Intra-operative (vascular/epicardial)	N	N	N		N	N	N	
	Intra-operative (Neuro)	N	N	N	ļ	N	N	N	
	Laparoscopic				ļ. <u> </u>				
Fetal Imaging	Pediatric	N	N	N		N		N	
& Other	Small Organ (Thyroid)	N	N	N		N	N	N	
	Neonatal Cephalic	<u> </u>							
	Adult Cephalic	1							
	Trans-rectal	<u> </u>		<u> </u>					
	Trans-vaginal	<u> </u>	<u> </u>						
	Trans-urethral								
	Trans-esoph. (non-Card.)	<u> </u>	<u> </u>	<u> </u>					
	Intra-luminal								
	Other (Specify)								
	Cardiac Adult								
Cardiac	Cardiac Pediatric								
	Trans-esoph. (Cardiac)								
	Other (Specify)								
Peripheral	Peripheral vessel	N	N	N		N	N	N	
Vessel	Other (Specify)								
	Musculo-skel (conventional)	N	N	N		N	N	N	
	Musculo-skel (superficial)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

\*Other modes: Amplitude Doppler, Panoramic, Directional Angio Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

Previous submission: K001711 for Intraoperative (cardiovascular & neurological), Small parts, Musculo-skeletal (conventional). K990330 for Intraoperative (Cardiovascular), Pediatric, Small Parts, Cardiac, Peripheral Vascular,

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Concurrence of Center for Devices and Radiological	gical Health, Office of Device Evaluation
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Prescription Use (Per 21 CFR 801.109)	(Division Sign-Off)
	Division of Reproductive, Abdominal,
	and Radiological Devices
	510(k) Number

210(k) Numbe	r: K
	Philips Medical Systems M2540 Diagnostic Ultrasound System
Transducer:	21422A Sector transducer
Intended Lise:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)	
Ophthalmic	Ophthalmic	N		N	N	Ň	N	N	
Орниципи	Fetal	N	N	N		N	N ·	N	
	Abdominal	N	N	N	N	N	N	N	
	Intra-operative (Specify)		<b>—</b>	<del>                                     </del>					
•	Intra-operative (Neuro)			1					
	Laparoscopic								
Fetal Imaging	Pediatric	N	N	N	N	N	. N	N	
& Other	Small Organ (Specify)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	
•	Trans-rectal								
•	Trans-vaginal					<u> </u>	<u> </u>		
	Trans-urethral		<u> </u>			<b></b>		ļ	
	Trans-esoph. (non-Card.)		<u>L</u>		ļ <u>.</u>				
	Intra-luminal		<u> </u>	<u> </u>		ļ		<u> </u>	
	Other (Gynecological)						<del> </del>	37	
	Cardiac Adult	N	N	N	N	N	N	N N	
Cardiac	Cardiac Pediatric	N	N	N	N	N	N	N N	
	Trans-esoph. (Cardiac)	<u> </u>		ļ	ļ	<u> </u>		ļ	
	Other (Specify)					<u> </u>			
Peripheral	Peripheral vessel				<u> </u>		ļ		
Vessel	Other (Specify)		<u> </u>	ļ		<u> </u>	ļ		
	Musculo-skel (conventional)		ļ	<del>                                     </del>	ļ	<u> </u>	<u> </u>		
	Musculo-skel (superficial)				1: -		<u> </u>	<u></u>	

N= new indication; P= previously cleared by FDA; E= added under Appendix E

\*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

Previous submission: None.

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Prescription	Use	(Per 21	CFR	801.10	)9)
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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

10(k) Number KD/4/4/

510(k) Number	er: K
System:	Philips Medical Systems M2540 Diagnostic Ultrasound System

Transducer: 21425A Curved linear array transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)	<u> </u>						
	Intra-operative (Neuro)							
	Laparoscopic	<u> </u>						
Fetal Imaging	Pediatric	N	N	N		N	N	N
& Other	Small Organ (Specify)	<u> </u>						
	Neonatal Cephalic	<u> </u>	<u> </u>					
	Adult Cephalic	<u> </u>						
	Trans-rectal							
	Trans-vaginal	<u> </u>						
	Trans-urethral	<u> </u>						ļ <u>.</u>
	Trans-esoph. (non-Card.)	<u> </u>					·	·
	Intra-luminal	<u> </u>				<u> </u>		
	Other (Gynecological)	N	Ň	N		N	N	N
	Cardiac Adult							
Cardiac	Cardiac Pediatric	l						
	Trans-esoph. (Cardiac)	1						
	Other (Fetal)	N	N	N		N	N	N
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							
	Musculo-skel (conventional)							
	Musculo-skel (superficial)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E	
*Other modes: Angio, Panoramic, Harmonics (Tissue & Contrast), 3-D Imaging, Directional Angio Imaging	
Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color	
Previous submission: None.	

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal,

and Radiological Devices KO14-191

510(k) Numbe	я: <u>К</u>								
	Philips Medical Systems M2540 Diagnostic Ultrasound System								
Transducer:	21446A Endocavity trans	sduce	r						
Intended Use:	Diagnostic ultrasound imag	ging o	r fluic	i f <u>low a</u>	nalysis (	of the hum	an body as f	ollows:	
Clinical Applicati		Mode of Operation							
General	Specific	В	M	PWD	CWD	Color	Combined	Other*	
(Track I Only)	(Tracks I & III)	<u> </u>	<del></del>	<u> </u>		Doppler	(Specify)	(Specify)	
Ophthalmic	Ophthalmic Ophthalmic	<u> </u>		<u> </u>		<del></del>	<u> </u>		
	Fetal	N	N	N	<u> </u>	N	N	N	
	Abdominal		<u> </u>	<u> </u>	<del> </del>	ļ	<u> </u>		
	Intra-operative (Specify)	<u></u>				<u> </u>	<u> </u>		
	Intra-operative (Neuro)		<u> </u>	<u> </u>	1	<u> </u>			
	Laparoscopic				<u> </u>			i	
Fetal Imaging	Pediatric		<u> </u>		<u> </u>	<u> </u>			
& Other	Small Organ (Specify)		<u></u>						
	Neonatal Cephalic								
1	Adult Cephalic					<u> </u>			
<u> </u>	Trans-rectal	N	N	N		N	N	N	
! 	Trans-vaginal	N	N	N :		N	N	N	
·	Trans-urethral				<u> </u>				
·	Trans-esoph. (non-Card.)								
, 	Intra-luminal		<u> </u>						
<u> </u>	Other (Gynecological)	N	N	N		N	N	N	
	Cardiac Adult								
Cardiac	Cardiac Pediatric	<u></u>							
!	Trans-esoph. (Cardiac)	<u> </u>	<u> </u>						
	Other (Specify)	<u> </u>		<u>.                                    </u>	]		<u> </u>		
Peripheral	Peripheral vessel								
Vessel	Other (Specify)								
	Musculo-skel (conventional)		[						
,	Musculo-skel (superficial)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

\*Other modes: Angio, Panoramic, 3-D Imaging, Directional Angio Imaging

Combined modes: Duplex = 2D + Doppler; Triplex = 2D + Doppler + Color

Previous submission: None.

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Vanne	NC mondon
(Division Sign-Off)	1
Division of Reproductive, and Radiological Devices	
510(k) Number	KO14191